REMARKS/ARGUMENTS

The Pending Claims

Claims 36, 37, and 40-70 are pending and are directed to a bacterial artificial chromosome (BAC) and a method of producing and mutagenizing same.

The Amendments to the Claims

Claims 51-56 have been amended to recite that the cell is "isolated," as suggested in the Office Action. Accordingly, no new matter has been added by way of these amendments.

The Office Action

Claims 51-56 are rejected under 35 U.S.C. § 101 for allegedly encompassing non-statutory subject matter. Claims 36, 37, 40, 42, 48, 51, 54, 57, 58, and 64-66 are rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Messerle et al., *J. Mol. Med.*, *74*: B8 (1996) ("the Messerle reference"). Claims 41, 43, 44, 45-47, 49, 50, 52, 53, 55, 56, 59, 60-63, and 67-70 are rejected under 35 U.S.C. § 103 as allegedly unpatentable over the Messerle reference alone or in combination with one or more of the following secondary references: Tomkinson et al., *J. Virol.*, *67*: 7298-7306 (1993) ("the Tomkinson reference"), Ehtisham et al, *J. Virol.*, *67*: 5247-5252 (1993) ("the Ehtisham reference"), Gage et al., *J. Virol.*, *66*: 5509-5515 (1992) ("the Gage reference"), Roizman et al., *Science*, *229*: 1208-1214 (1985) ("the Roizman reference"), Chen et al., *Mol. Cell. Biol.*, *7*: 2745-2752 (1987) ("the Chen reference"), and Luckow et al., *J. Virol.*, *67*: 4566-4579 (1993) ("the Luckow reference"). Reconsideration of these rejections is respectfully requested.

Discussion of Rejection Under 35 U.S.C. § 101

Claims 51-56 have been rejected under Section 101 as allegedly encompassing non-statutory subject matter. Applicants disagree with the Office Action's assertion that the rejected claims encompass cells that are naturally present in a human being. Nevertheless, claims 51-56 have been amended to refer to an "isolated" cell. Accordingly, the rejection under Section 101 should be withdrawn.

Discussion of Rejection Under 35 U.S.C. § 102

Claims 36, 37, 40, 42, 48, 51, 54, 57, 58, and 64-66 have been rejected under Section 102(b) as allegedly anticipated by the Messerle reference. This rejection is traversed for the reasons set forth below.

According to the Office Action, the rejected claims were previously indicated as allowable over the Messerle reference because the claims were not construed in their broadest reasonable interpretation. In this respect, the Office Action alleges that the definition of the phrase "an infectious herpes virus genomic sequence" in the specification only refers to sequences that are *necessary*, but not *sufficient*, for virus replication and packaging. As such, the claims allegedly encompass a BAC comprising *any* gene necessary for herpes virus replication and packaging. The Messerle reference allegedly anticipates the subject matter of claim 36 because it discloses two BAC/MCMV hybrid vectors, each of which comprise BAC sequences and an infectious viral genomic sequence larger than 200 kb. Infectious viral progeny is obtained upon co-transfection of both plasmids into cells.

Applicants respectfully submit that the Office Action's interpretation of the rejected claims is not consistent with the disclosure of the instant application. Indeed, the specification describes genomic sequences that are both *necessary and sufficient* for virus replication and packaging. The phrase "infectious viral genomic sequence" is defined in the specification as "the complete genome and *those* parts of the genome of a virus that are indispensable for replication and packaging in a host organism or cell" (see page 3, first complete paragraph). The use of the definite article "those" in reference to "parts of the genome of a virus" clearly indicates that the phrase "infectious herpes virus genomic sequence" does *not* encompass *any* part of a viral genome necessary for replication. Rather, such language indicates that the phrase "infectious herpes virus genomic sequence" encompasses *all* sequences that are sufficient for viral replication and packaging.

Moreover, the specification states that the BAC vectors disclosed therein comprise "*at least those parts* of the genome of a virus that are required for replication and packaging" (see pages 2 and 3, bridging paragraph). The phrase "at least those parts" clearly indicates a specific defined subset of all of the sequences comprising the herpes virus genome, namely, those sequences required for replication and packaging. In other words, the term "at least"

indicates that the BAC contains the minimum number of sequences required for virus replication and packaging, i.e., those sequences that are sufficient for virus replication and packaging.

Applicants note that the term "infectious" is used interchangeably with the term "replication-capable" in the instant application, which is further evidence that the phrase "infectious herpes virus genomic sequence" encompasses sequences that are sufficient for virus replication. In view of the foregoing, one of ordinary skill in the art would interpret the rejected claims as encompassing a BAC comprising a complete infectious herpes virus genomic sequence or sequences that are necessary and sufficient for virus replication. Any other interpretation of the rejected claims would be unreasonable in light of the specification.

Given the broadest reasonable interpretation of the rejected claims, the Messerle reference does not disclose the subject matter of the rejected claims. In this respect, the Messerle reference discloses transfecting eukaryotic cells with two BAC/MCMV hybrid plasmids which do not contain infectious viral genomic sequences. In particular, the Messerle reference states that "[t]ransfection of each plasmid alone into eukaryotic cells did not result in the production of a progeny." Thus, the two individual plasmids described by the Messerle 1996 reference do not contain an infectious herpes virus genomic sequence capable of being replicated and packaged in the viral host. Infectious viral progeny can only be obtained by co-transfection of both plasmids. Moreover, one of ordinary skill in the art following the teachings of the Messerle reference could not have isolated a homogenous plasmid preparation from the transfected cells. In this regard, the two plasmids disclosed in the Messerle reference recombine in the cell, thereby resulting in different recombination products. Isolating the recombined plasmid constructs from the cells would lead to a heterogeneous mixture of plasmids.

This is in distinct contrast to the present invention, which provides a BAC containing bacterial nucleic acid sequences and an infectious herpes virus genomic sequence larger than 100 kb, wherein the BAC enables replication of the infectious herpes virus genomic sequence in a host cell. Thus, the Messerle reference does not disclose the subject matter of claims 36, 37, 40, 42, 48, 51, 54, 57, 58, and 64-66. Accordingly, the rejection under Section 102(b) should be withdrawn.

Discussion of Rejections Under 35 U.S.C. § 103

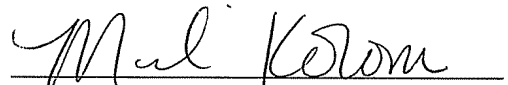
Claims 41, 43, 44, 45-47, 49, 50, 52, 53, 55, 56, 59, 60-63, and 67-70 have been rejected under Section 103 as allegedly unpatentable over the Messerle reference alone or in combination with one or more secondary references. This rejection is traversed for the reasons set forth below.

Claims 41, 43, 44, 45-47, 49, 50, 52, 53, 55, 56, 59, 60-63, and 67-70 directly or indirectly depend from claim 36. As discussed above, the Messerle reference does not disclose or suggest the subject matter of claim 36. As a result, the Messerle reference does not disclose or suggest the subject matter of claims 41, 43, 44, 45-47, 49, 50, 52, 53, 55, 56, 59, 60-63, or 67-70. None of the secondary references cited by the Office Action compensate for the deficiencies of the Messerle reference. In this respect, none of the Tomkinson, Ehtisham, Gage, Roizman, Chen, or Luckow references discloses or suggests a BAC containing bacterial nucleic acid sequences and an infectious herpes virus genomic sequence larger than 100 kb, wherein the BAC enables replication of the infectious herpes virus genomic sequence in a host cell. Accordingly, the Section 103 rejection should be withdrawn.

Conclusion

Applicants respectfully submit that the patent application is in condition for allowance. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned agent.

Respectfully submitted,



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